II. REJECTION OF CLAIMS 1--62 UNDER 35 USC 103(a) AS UNPATENTABLE OVER HAMILTON et al. (US 5,797,877) IN VIEW OF RAVENSCROFT, et al. (US 5,766,201).

The Examiner describes that Hamilton teaches the invention as claimed with the exception of the PTFE being porous while Ravenscroft et al. disclose that it was known to construct a balloon using a wrap of porous PTFE. The Examiner concludes that it would have therefore been obvious to use the porous PTFE as taught by Ravenscroft for the non-compliant material in the balloon of Hamilton, et al., especially in the event that the balloon is to be formed with a porous outer wrapped layer, as a porous PTFE wrap would provide a more lubricious surface by which the balloon might pass through an outer introducing catheter or through the vasculature in the event that the balloon was not sheathed, and/or when used to introduce a PTFE graft it would reduce surface tension and facilitate the graft's release from the balloon.

While Hamilton et al. teach the use of a thermoplastic elastomer in combination with a non-compliant polymeric material, they make absolutely no suggestion as to the use of porous polymeric materials and the possibilities of compliance in such materials. Further, they specifically teach thermoplastic elastomers and consequently teach away from the Applicants' preferred silicone elastomer, generally considered to be a thermoset material.

Applicants disagree particularly with the Examiner's interpretation of the Ravenscroft et al. passage at col. 2, lines 54-62. This does not teach that the spiral wrapping of Ravenscroft et al. is made from porous PTFE. Ravenscroft et al. describe a catheter balloon, in the form of a conventional inelastic balloon of PET (polyethylene terephthalate), that is provided with a separate helical wrap of a preferably elastic strip. This strip is elastically stretched when the balloon is expanded and elastically recovers when the expandable member is collapsed, thereby refolding the inelastic balloon. The wrap is not attached to the surface of the balloon, but is separate and attached only at its ends to the adjacent catheter shaft.

This modified catheter balloon is described as being useful for delivering an endoprosthesis in a compacted configuration to a desired site in the vasculature and expanding the endoprosthesis for implantation at that site by inflation of the balloon (col. 1, lines 50-65). It is further stated that the prosthesis may be an expandable PTFE graft (col. 3, lines 49-51, col. 4, lines 52-54), these are typically a porous expanded PTFE vascular graft such as a GORE-TEX® Vascular Graft. The porous PTFE referred to by Ravenscroft et al. at the passage referenced by the Examiner (col. 2, lines 54-62) is such a porous PTFE graft, and not the material of the helical wrap. The referenced section (col. 2, lines 54-62) states:

"In addition, the [helical] wrap may have a slippery surface compared to conventional balloon materials, such as PET, so that a polymer prosthesis is readily released from the balloon after it is expanded. (The stickiness between PET and PTFE is believed to be caused by surface tension interaction between these two smooth-surface materials or due to localized vacuum effects caused by the porous nature of the PTFE.) Further, in cases where the wrap exhibits elasticity, it may reduce the profile of the balloon upon inflation by aiding balloon refolding."

Ravenscroft et al. are referring to the porous nature of the PTFE endoprosthesis as used previously (with regard to their own work) with PET balloons. They are not referring to the material of the helical wrap. While they mention that the helical wrap might be made from or coated with PTFE (col. 5, lines 64-65 and col. 6, lines 7-10), they never teach or suggest the use of porous PTFE (or, for that matter, any other porous material) for the helical wrap. Indeed, when Ravenscroft et al. speak of using PTFE as the helical strip material, they note that PTFE is non-elastic and that "...the strip does not recover elastically upon deflation" (col. 5, line 67). Clearly, it was not contemplated to create a balloon itself from a composite of a porous polymer and an elastic material whereby a balloon with elastic behavior properties results. While Ravenscroft et al. speak of their strip in its elastic embodiment (i.e., not PTFE) as an aid in refolding their inelastic balloon during deflation (e.g., col. 2, lines 60-62), the balloon of the present invention, having elastic behavior, does not refold but simply assumes its preinflation, circular cross section without folds.

In short, Hamilton et al. teach the use of thermoplastic elastomers in combination with other non-compliant, non-porous polymeric materials to make a balloon. Ravenscroft et al. make no suggestion whatsoever as to the creation of a catheter balloon with elastic behavior characteristics or to the use of porous polymeric materials to make a balloon. Neither of the cited references makes any suggestion to create a catheter balloon from a porous polymeric material in combination with an elastomer, nor do they suggest that a compliant balloon with elastic behavior characteristics might be made from porous polymers such as porous PTFE. The claimed invention does not reside in the cited references, either alone or in combination.

CONCLUSION

Applicants submit that their claims are patentable over the cited art and are in condition for allowance. Accordingly, Applicants respectfully request reexamination and passage of the claims to issuance.

If any issues of substance are seen to remain following consideration of the arguments presented herein, in the interest of expedient resolution the Examiner is requested to telephone the Applicants' representative at the telephone number given below, between the hours of 8AM to 5PM Mountain Standard Time.

Respectfully submitted,

Wayne D. House

Wayne D. House 34,623
W. L. Gore & Associates, Inc.
551 Paper Mill Road
P.O. Box 9206
Newark, DE 19714-9206
(520) 526-3030

Date: October 12, 2000